

# Healthy Living/Health Services Subcommittee

## Long-Term Antibiotics and Lyme Disease

October 6, 2010

### Co-Chairs:

Senator Patricia S. Ticer

Delegate John M. O'Bannon, III

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## Authority for Study

- ▶ House Bill 512 was introduced by Delegate Rust during the 2010 General Assembly Session:
  - to allow licensed physicians to prescribe, administer, or dispense long-term antibiotic therapy to a patient diagnosed with Lyme disease.
  - to specify that the Board of Medicine shall not initiate a disciplinary action against a licensed physician solely for prescribing, administering, or dispensing long-term antibiotic therapy to a patient clinically diagnosed with Lyme disease.
- ▶ HB 512 was continued to 2011 in HWI, and sent to the JCHC for further study.

## What is Lyme Disease?

- ▶ A bacterial illness transmitted by a bite from the black-legged tick, or “deer tick”.
- ▶ Between 3–30 days after being bitten by an infected tick, 70–90% of people develop a “bull’s eye rash” called erythema migrans (EM).
- ▶ Lyme Disease (LD) may also cause headache, fever, muscle and joint aches, and fatigue.
- ▶ If left untreated, LD may progress to affect the joints, nervous system, or heart.

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### What is Lyme Disease?

A Tick-borne bacterial disease

#### 3 Stages of Infection

- Early Localized Infection (3-30 days)  
Bull’s-eye rash, muscle or joint aches, fever, headache
- Early Disseminated Infection (1- 4 months)  
Severe headaches, pain, neurological symptoms
- Late Disseminated Infection (3 months to years)  
Severe arthritis and swelling of large joints, pain, neurological and cognitive disorders



## Lyme Disease Diagnosis

- ▶ Diagnosis is based on symptoms, objective physical findings (such as EM, facial palsy, or arthritis), and a history of possible tick exposure.
- ▶ The CDC recommends a 2-step process when testing blood for LD.
  - The first uses an ELISA. If it is positive, then,
  - The second step uses an immunoblot such as a Western blot.
- ▶ Some labs use other testing but the CDC does not recommend these tests.

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## Treatment of Lyme Disease

- ▶ The National Institutes of Health (NIH) has conducted multiple studies on the treatment of LD:
  - Most patients can be cured with a few weeks of oral antibiotics.
  - Patients treated with antibiotics in the early stages of infection usually recover rapidly and completely.
  - Some patients (usually diagnosed in later stages) may benefit from a second 4-week course of antibiotic treatment
  - Longer courses of antibiotics have been linked to serious complications, including death.

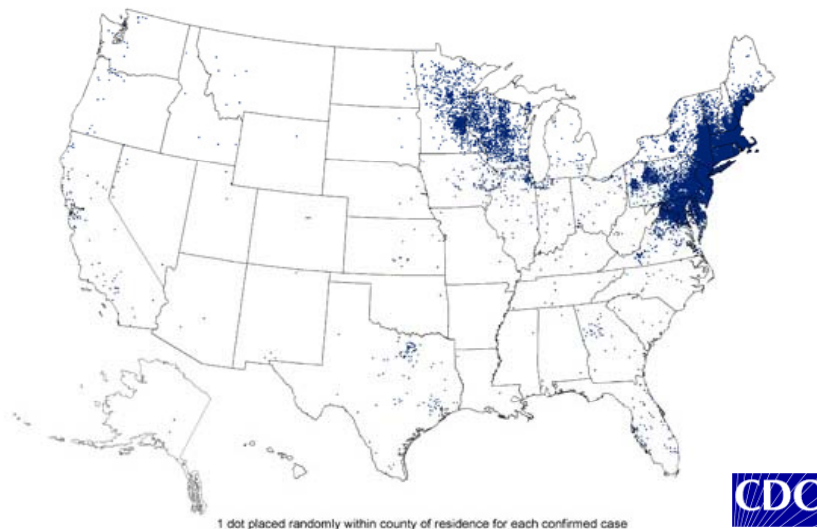
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## Lyme Disease Cases Increasing

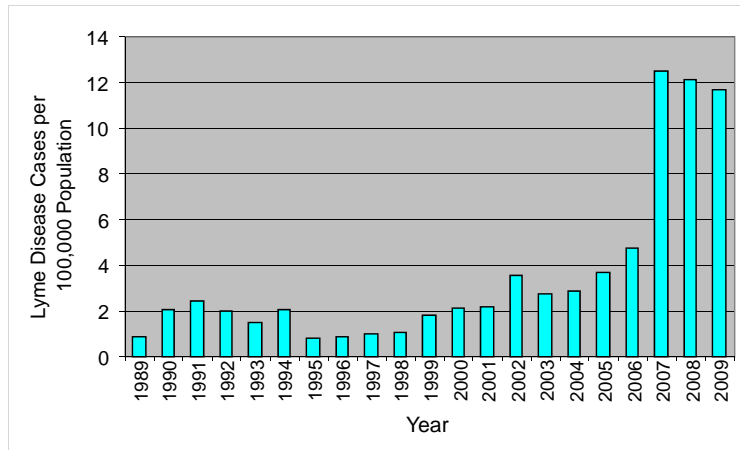
- ▶ Lyme disease in Virginia is spreading west and south after having mostly been concentrated in the northern part of the state.
- ▶ In 2009, 908 cases were reported.
- ▶ Governor McDonnell recognized May 2010 as Lyme Disease Awareness Month.

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Reported Cases of Lyme Disease -- United States, 2008



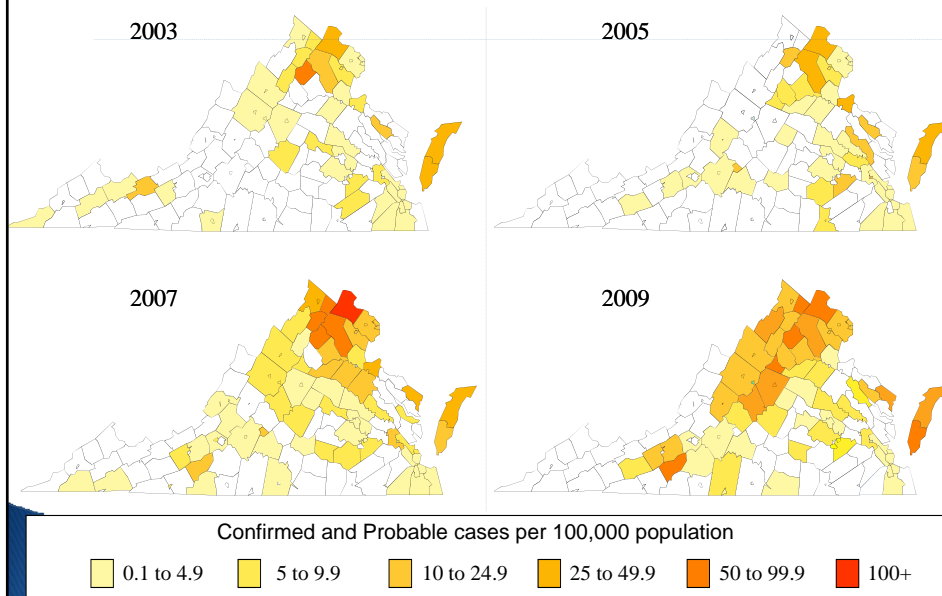
## Lyme Disease Cases in Virginia, 1989 - 2009



Source: Dr. Keri Hall, Virginia Department of Health, "Lyme Disease Tracking and Prevention." (September 28, 2010).

## Newly Identified Lyme Disease Cases by County

Source: Dr. Keri Hall, Virginia Department of Health, "Lyme Disease Tracking and Prevention." (September 28, 2010).



## Role of the Virginia Department of Health

- ▶ Monitor the annual number and geographic distribution of newly identified Lyme disease cases in Virginia.
- ▶ Prevent Lyme disease through education.
- ▶ In FY09, VDH received approximately \$19,000 for education and prevention.

Source: Dr. Keri Hall, Virginia Department of Health, "Lyme Disease Tracking and Prevention." (September 28, 2010).

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## Reporting Requirements for Lyme Disease

- ▶ Code of Virginia 32.1–36 requires “every physician practicing in this Commonwealth who shall diagnose or reasonably suspect that any patient of his has any disease required by the Board to be reported and every director of any laboratory doing business in this Commonwealth that performs any test whose results indicate the presence of any such disease shall make a report within such time and in such manner as may be prescribed by regulations of the Board.”

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## Reporting Requirements for Lyme Disease

- ▶ 12VAC5-90-80 includes Lyme Disease as one of the diseases to be reportable to the VDH, within 3 days of suspected or confirmed diagnosis.

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## Reporting Requirements for Lyme Disease

- ▶ VDH uses the CDC's LD Surveillance Case Definition:
  - Necessary case information:
    - Lyme-associated symptoms including EM if present, date of onset, and complete lab testing results.
  - Necessary lab results:
    - Positive or equivocal results from ELISA as well as positive Western Blot IgM if the blood was drawn within 30 days of onset, or
    - Positive Western Blot IgG, if blood was drawn more than 30 days after onset.

Source: Dr. Keri Hall, Virginia Department of Health, "Lyme Disease Tracking and Prevention." (September 28, 2010).

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## Lyme Disease Prevention

- ▶ Avoid tick habitats
- ▶ Dress appropriately
- ▶ Use repellants
- ▶ Do tick checks
- ▶ Remove ticks properly
- ▶ Know the early signs of the disease.
- ▶ Additionally, keeping landscapes manicured with clear edging between the manicured law and the forest.

▶ Source: Dr. Keri Hall, Virginia Department of Health, "Lyme Disease Tracking and Prevention." (September 28, 2010).

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## What is Chronic Lyme Disease?

- ▶ It is a term often used in patients who have non-specific symptoms (like fatigue and pain) after treatment for LD, but who have no evidence of active infection with *B. burgdorferi*.
- ▶ Physicians prefer to describe these patients as having post-Lyme disease syndrome (PLDS).

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## What is Chronic Lyme Disease?

- ▶ The National Institute of Allergy and Infectious Diseases (NAID), through NIH funded 3 studies on the treatment of PLDS.
  - These studies reinforced that patients with PLDS have a severe impairment in overall physical health and quality of life; however the results showed no benefit from prolonged antibiotic therapy, and indicated potential dangerous side effects.

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## The Infectious Diseases Society of America (IDSA) Guidelines

- ▶ Issued voluntary treatment guidelines for LD in 2006.
- ▶ The guidelines recommend a short course of antibiotics for nearly all patients with Lyme disease.
- ▶ The guidelines recommend against repeated, long-term antibiotic therapy with brand name drugs in favor of generic drugs and diagnostic tests, eliminating the possibility of profit for panel members.

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## IDSA Guidelines

- ▶ The Connecticut AG began investigating IDSA to determine if dissenting views were disregarded when the guidelines were developed and if any financial interests among the writers of the guidelines existed.
- ▶ A settlement was reached that called for a new panel of physicians to fully review the Lyme disease guidelines.
- ▶ In April 2010, the independent review panel voted that no changes needed to be made to the 2006 guidelines.

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## IDSA Guidelines

- ▶ The panel concluded that, “for nearly all patients, a short course of antibiotics is an effective treatment for LD. Studies have proven that long-term antibiotic treatment, which is usually given through a needle and a catheter, is ineffective, expensive, and potentially harmful. The overuse of antibiotics also contributes to an important public health threat: the development of drug-resistant infections that are difficult if not impossible to treat.”

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## Alternative Explanations

- ▶ “Lyme-literate” doctors, who believe that Lyme can be a persistent and relapsing infection often treat their patients with combinations of antibiotics over a long period until symptoms resolve, not according to the short-term treatment schedules set forth by the IDSA.
- ▶ These doctors offer alternative research and studies that suggest post-Lyme syndrome could result from an autoimmune reaction to the Lyme bacteria; or certain genetic traits are at play, and finally that the Lyme bacterium is capable of surviving the short-term doses of antibiotics.

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## Alternative Explanations

- ▶ Lyme advocates also point to studies that suggest connections between Lyme infections and multiple sclerosis, lupus, Lou Gehrig’s disease, Parkinson’s, recurrent meningitis, schizophrenia, dementia and autism. Why LD is often called the Great Imitator.
- ▶ Lyme literate physicians argue that not everything is known about Lyme disease and more research is needed, and physicians and the community need to more open-minded in treating post Lyme disease.

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## **The International Lyme and Associated Diseases Society (ILADS)**

- ▶ In response to the IDSA, medical professionals who tout long-term treatment of a resilient Lyme infection have organized themselves into the ILADS.
- ▶ As the debate continues, ILADS doctors who disagree with the short treatment recommendations of the IDSA sometimes find themselves investigated and tried by their state medical licensing board for breaking with the IDSA.

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## **Impetus for this Bill**

- ▶ A constituent was unable to receive treatment in Virginia, and was under the impression that the physicians avoided treating Lyme patients because he/she feared disciplinary action by the Board of Medicine.
- ▶ There have been cases of physicians in other states being disciplined for treating Lyme Disease patients with long-term antibiotics.
  - In most of the cases, the doctors did not establish a case for Lyme Disease.

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## Virginia Board of Medicine

- ▶ To date, there have been no disciplinary proceeding by Virginia Board of Medicine against a physician for treating LD with long-term antibiotics.
- ▶ The case of the Eastern Shore physician recently in the news, involves being disciplined for prescribing narcotics. The physician is still able to administer long-term antibiotic treatment to Lyme Disease patients.

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## Rhode Island

- ▶ Rhode Island enacted a bill to make Lyme disease awareness and prevention resources available for all public school students.
- ▶ Rhode Island also enacted a bill mandating insurance companies to cover long term antibiotic treatment of Post-Lyme Disease.

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## New York

- ▶ Passed a resolution in 2002 requesting that insurance companies and the Office of Professional Medical Conduct cease and desist from targeting physicians who fall on one side or the other of this controversy, until such time as medical research and the medical community have determined the appropriate parameters for the diagnosis and treatment of tick-borne illnesses.

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## Connecticut

- ▶ Passed a doctor protection bill that protects licensed Lyme treating physicians in Connecticut from prosecution by the Medical Board solely on the basis of a clinical diagnosis and/or for treatment of long-term Lyme disease.
- ▶ Clinical diagnosis is defined as being determined by a physician “that is based on knowledge obtained through the medical history and physical examination alone, or in conjunction with the testing that provides supportive data for such clinical diagnosis.”
- ▶ The purpose was to encourage more physicians knowledgeable about Lyme Disease to practice within Connecticut.

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## Massachusetts

- ▶ The 2011 Massachusetts state budget includes an amendment which will protect physicians who treat Lyme disease for longer than 30 days.
- ▶ The bill is similar to physician protection legislation which was passed in Connecticut.

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## Minnesota

- ▶ Minnesota considered a bill that was similar to the Connecticut law.
  - It passed the Senate, but was withdrawn in the House.
- ▶ After strong opposition by the Medical Board, the patron and the Lyme Advocacy groups agreed to work with the Medical Board to come up with a policy and keep it out of the statutory arena.

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## New Hampshire

- ▶ A New Hampshire bill died in conference committee during their most recent General Assembly Session.
  - The bill would have established a committee to investigate and assess access to viable and credible alternative medical practices and protocols to Lyme Disease.

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## Federal Action

- ▶ H.R. 1179 introduced this year and co-sponsored by Rep. Frank Wolf, would provide for the expansion of federal efforts concerning the prevention, education, treatment and research activities related to Lyme and other tick-borne diseases, including the establishment of a Tick-Borne Diseases Advisory Committee.
  - It has been referred to the House, Energy and Commerce Committee.

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## Federal Action

- ▶ Language was included in the Appropriations bill, signed by President Obama in December 2009, to provide funds for the development of more accurate tests, better surveillance and physician education.

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## Additional Activity

- ▶ Institute of Medicine Lyme Committee on Lyme Disease and Other Tick-Borne Diseases: State of the Science is holding a workshop on October 11-12 in Washington D.C.
- ▶ Governor McDonnell's Lyme Disease Task Force

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## Policy Options

- ▶ **Option 1:** Take no action.
- ▶ **Option 2:** By letter of the JCHC Chairman, to the Health, Welfare and Institutions Committee, indicate support for HB 512.
- ▶ **Option 3:** Introduce a budget amendment (language and funding) to provide the Department of Health with additional funding for education and prevention efforts.

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## Public Comments

- ▶ Written public comments on the proposed options may be submitted to JCHC by close of business on October 22, 2010 via:
  - E-mail: [jhoyle@jchc.virginia.gov](mailto:jhoyle@jchc.virginia.gov)
  - Fax: 804-786-5538
  - Mail: Joint Commission on Health Care  
P.O. Box 1322  
Richmond, Virginia 23218
- ▶ Comments will be summarized and reported during the November 3<sup>rd</sup> Decision Matrix meeting.

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